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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/617,428	07/10/2003	Scott Schewe	S63.2-10941-US01	3232
490 75	7590 07/26/2006		EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summany		Application No.	Applicant(s)				
		10/617,428	SCHEWE ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Mark Eashoo, Ph.D.	1732				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REF CHEVER IS LONGER, FROM THE MAILING asions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory perior re to reply within the set or extended period for reply will, by state eply received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION 1.136(a). In no event, however, may a reply be tind will apply and will expire SIX (6) MONTHS from ute, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status							
1)⊠	Responsive to communication(s) filed on 12	May 2006.					
·	This action is FINAL . 2b)⊠ This action is non-final.						
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
4)⊠ Claim(s) <u>1-42</u> is/are pending in the application.							
<u>-</u>	4a) Of the above claim(s) <u>1-9 and 38-42</u> is/are withdrawn from consideration.						
5)	5) Claim(s) is/are allowed.						
6)⊠	Claim(s) 10-37 is/are rejected.						
7)	Claim(s) is/are objected to.						
8)□	8) Claim(s) are subject to restriction and/or election requirement.						
Applicati	on Papers	,					
9) The specification is objected to by the Examiner.							
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	nder 35 U.S.C. § 119						
a)[Acknowledgment is made of a claim for foreignal All b) Some * c) None of: 1. Certified copies of the priority documents. 2. Certified copies of the priority documents. 3. Copies of the certified copies of the priority application from the International Bure ee the attached detailed Office action for a list	nts have been received. nts have been received in Applicationity documents have been received au (PCT Rule 17.2(a)).	on No ed in this National Stage				
2) 🔲 Notice 3) 🔯 Inform	(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/06 No(s)/Mail Date 4ea.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:					

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claim group II, claims 10-37, in the reply filed on 12-MAY-2006 is acknowledged. The traversal is on the ground(s) that the claim groupings are closely related. This is not found persuasive because the examination of process claims does not require the same patentable weight or consideration for structural limitations in either a product made by the process or an apparatus used in the process.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9 and 38-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected claim groupings, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12-MAY-2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 15 appears to recite an intended use of the product of the process of claim 10 without adding an additional process step. As such, the claim is indefinite because it cannot be clearly ascertained if applicant intended a step of forming the tubing segment into a catheter balloon. It is noted that if applicant is merely reciting an intended use of the product and not an additional process step, then the claim is also indefinite because it is unclear how the process of claim 15 (ie. step-wise limitation) is further limited from the process of claim 10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-12, 14, 18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepin et al. (US Pat. 5,614,136) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 10: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45).

Regarding claim 11: Pepin et al. also teaches cutting a predetermined locations (Figs. 6-7, element 80).

Regarding claims 12, 21, and 22: Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies (Figs. 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations).

Regarding claim 14: The terms 'proximal' and 'distal' are relative terms depending upon the use of the tubular product and as such have little patentable weight when directed to the process other than that fact that there are two regions. As such, it is submitted that the high pulling speeds which would cause higher drawing and smaller diameters (ie. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

Regarding claim 18: Pepin et al. also teaches extruding a single polymer (5:63-67).

Regarding claim 20: Pepin et al. also teaches a polymeric blend (8:66-67).

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepin et al. (US Pat. 5,614,136) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 23: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7). Pepin et al. specifically teaches that the varying the speed of the puller or drawing rate changes the volume of extruded material in a given length (6:5-24) which is essentially the rate of extrusion.

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45).

Regarding claims 24-25: Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies including tapers or waist portions (Figs. 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations). It is submitted that the high pulling speeds which would cause higher drawing and smaller diameters (ie. at a constant extrusion rate) would

experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

Page 4

Claims 26-28, 30, 31, 35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepin et al. (US Pat. 5,614,136) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 26: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45). It is submitted that the high pulling speeds which would cause higher drawing and smaller diameters (ie. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

The examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

Regarding claims 27-28: Again, the examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

<u>Regarding claims 30-31</u>: Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies (Figs. 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations).

Regarding claim 35: Pepin et al. also teaches extruding a single polymer (5:63-67).

<u>Regarding claim 37</u>: Pepin et al. also teaches a polymeric blend (8:66-67). It is submitted that a blend requires at least two materials.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pepin et al. (US Pat. 5,614,136) in view of Wand et al. (US Pat. 5,535,388) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 15: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45).

Pepin et al. does not teach shaping a parison having a variable wall thickness into a catheter balloon.

However, Wand et al. teaches shaping a parison having a variable wall thickness into a catheter balloon (2:30-3:25).

Pepin et al. and Wand et al. are combinable because they are from the same field of endeavor, namely, the production of medical tubing. At the time of invention a person of ordinary skill in the art would have found it obvious to have shaped a parison having a variable wall thickness into a catheter balloon, as taught by Wand et al., in the process of Pepin et al., and would have been motivated to do so in order to form another product using the same production line (ie. economic benefit).

<u>Regarding claims 16-17</u>: Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies (Figs. 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pepin et al. (US Pat. 5,614,136) in view of Di Luccio et al. (US Pat. 4,720,384) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 13: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45).

Pepin et al. does not teach varying the gap length. However, Di Luccio et al. teaches varying the gap length (8:35-45). Pepin et al. and Di Luccio et al. are combinable because they are concerned with a similar technical difficulty, namely, the extrusion of medical grade polymers and cooling the extrudate in a bath. At the time of invention a person of ordinary skill in the art would have found it obvious to have varied the gap length, as taught by Di Luccio et al., in the process of Pepin et al., and would have been motivated to do so since Di Luccio et al. suggests that the gap length can be adjusted to create desired physical properties in the extruded product.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pepin et al. (US Pat. 5,614,136) in view of Tiernan et al. (US Pat. 6,579,484) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 19: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45).

Pepin et al. does not teach co-extruded multilayer tubing. However, Tiernan et al. teaches co-extruded multilayer tubing (abstract and Figs. 7-9). Pepin et al. and Tiernan et al. are combinable because they are from the same field of endeavor, namely, the production of medical tubing. At the time of invention a person of ordinary skill in the art would have found it obvious to have co-extruded multilayer tubing, as taught by Tiernan et al., in the

process of Pepin et al., and would have been motivated to do so in order to form a product having desirable physical properties attributed to each of the materials (eg. lubricity and burst strength).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pepin et al. (US Pat. 5,614,136) in view of Di Luccio et al. (US Pat. 4,720,384) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 29: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45). It is submitted that the high pulling speeds which would cause higher drawing and smaller diameters (ie. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

The examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

Pepin et al. does not teach varying the gap length. However, Di Luccio et al. teaches varying the gap length (8:35-45). Pepin et al. and Di Luccio et al. are combinable because they are concerned with a similar technical difficulty, namely, the extrusion of medical grade polymers and cooling the extrudate in a bath. At the time of invention a person of ordinary skill in the art would have found it obvious to have varied the gap length, as taught by Di Luccio et al., in the process of Pepin et al., and would have been motivated to do so since Di Luccio et al. suggests that the gap length can be adjusted to create desired physical properties in the extruded product.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pepin et al. (US Pat. 5,614,136) in view of Wang et al. (US Pat. 5,556,383) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 33 and 34: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and

altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45). It is submitted that the high pulling speeds which would cause higher drawing and smaller diameters (ie. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

The examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

Pepin et al. does not teach using a polyester/polyether block copolymer or a polyamide/polyether/polyester. However, Wang et al. using a polyester/polyether block copolymer (Hytrel ®) or a polyamide/polyether/polyester (Pebax®) (4:40-67). Pepin et al. and Tiernan et al. are combinable because they are from the same field of endeavor, namely, the production of medical tubing. At the time of invention a person of ordinary skill in the art would have found used a polyester/polyether block copolymer or a polyamide/polyether/polyester in the process of making medical tubing, as taught by Wang et al., in the process of Pepin et al., and would have been motivated to do so because Wang et al. provides evidence that such materials a known equivalents for the same purpose (see MPEP § 2144.06).

Claim 36 is rejected, rendered obvious by Pepin et al. (US Pat. 5,614,136) in view of Tiernan et al. (US Pat. 6,579,484) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 36: Pepin et al. teaches the claimed process of forming a a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7).

Pepin et al. does not specifically teach that different orientations (ie. molecular orientation) occurs during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing /pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45). It is submitted that the high pulling

speeds which would cause higher drawing and smaller diameters (ie. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

The examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

Pepin et al. does not teach co-extruded multilayer tubing. However, Tiernan et al. teaches co-extruded multilayer tubing (abstract and Figs. 7-9). Pepin et al. and Tiernan et al. are combinable because they are from the same field of endeavor, namely, the production of medical tubing. At the time of invention a person of ordinary skill in the art would have found it obvious to have co-extruded multilayer tubing, as taught by Tiernan et al., in the process of Pepin et al., and would have been motivated to do so in order to form a product having desirable physical properties attributed to each of the materials (eg. lubricity and burst strength).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached form PTO-892.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Eashoo, Ph.D. whose telephone number is (571) 272-1197. The examiner can normally be reached on 7am-3pm EST, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Eashoo, Ph.D. Primary Examiner

21/71/00

Art Unit 1732/

me 21-Jul-06